IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS

August 27, 2021

KAREN MITCHELL

CLERK, U.S. DISTRICT

COURT

CASE NO. 3:21-CR-396-M

UNITED STATES (	OF AMERICA,
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Plaintiff,

v.

PROSUPPS USA LLC,

Defendant.

**DEFERRED PROSECUTION AGREEMENT** 

Defendant ProSupps USA LLC (the "Company") by its undersigned representatives, pursuant to authority granted by the Company's Managers reflected in Attachment B (the "Managers"), the United States Department of Justice, Civil Division, Consumer Protection Branch and the United States Attorney's Office for the Northern District of Texas (collectively, "the Government") enter into this deferred prosecution agreement ("the Agreement"), the terms and conditions of this Agreement are as follows:

# Criminal Information and Acceptance of Responsibility

1. The Company acknowledges and agrees that the Government will file the attached one-count criminal Information in the United States District Court for the Northern District of Texas charging the Company with one count of introduction of a misbranded food into interstate commerce in violation of Title 21, United States Code, Section 331(a) ("the Information"). In so doing, the Company: (a) knowingly waives its right to indictment on this charge, as well as all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution,

Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); (b) knowingly waives any objection with respect to venue to any charges by the United States arising out of the conduct described in the Statement of Facts attached hereto as Attachment A (the "Statement of Facts") and consents to the filing of the Information, as provided under the terms of this Agreement, in the United States District Court for the Northern District of Texas. The Government agrees to defer prosecution of the Company pursuant to the terms and conditions described below.

2. The Company admits, accepts, and acknowledges that it is responsible under United States law for the acts of its officers, directors, employees, and agents as charged in the Information, and as set forth in the Statement of Facts, and that the allegations described in the Information and the facts described in the Statement of Facts are true and accurate. The Company agrees that, effective as of the date it signs this Agreement, in any prosecution that is deferred by this Agreement, it will not dispute the Statement of Facts set forth in this Agreement, and, in any such prosecution, the Statement of Facts shall be admissible as: (a) substantive evidence offered by the Government in its case-in-chief and rebuttal case; (b) impeachment evidence offered by the government on cross-examination; and (c) evidence at any sentencing hearing or other hearing. In addition, in connection therewith, the Company agrees not to assert any claim under the United States Constitution, Rule 410 of the Federal Rules of Evidence, Rule 11(f) of the Federal Rules of Criminal Procedure, Section 1B1.1(a) of the United States Sentencing Guidelines ("USSG" or "Sentencing Guidelines"), or any other federal rule that the Statement of Facts should be suppressed or is otherwise inadmissible as evidence in any form.

# **Term of the Agreement**

3. This Agreement is effective for a period beginning on the date on which the Information is filed and ending two years from the date on which the Information is filed, as described in Paragraphs 18-19 below (the "Term"). The Company agrees, however, that, in the event the Government determines, in its sole discretion, that the Company has knowingly violated any material provision of this Agreement, or has failed to completely perform or fulfill each of the Company's obligations under this Agreement, an extension or extensions of the Term may be imposed by the Government, in its sole discretion, for up to a total additional time period of 12 months, without prejudice to the Government's right to proceed as provided in Paragraph 19 below. Any extension of the Agreement extends all terms of this Agreement for an equivalent period. Conversely, in the event the Government finds, in its sole discretion, that the other provisions of this Agreement have been satisfied, the Agreement may be terminated early. If the Court refuses to grant exclusion of time under the Speedy Trial Act, Title 18, United States Code, Section 3161(h)(2), the Term shall be deemed to have not begun, and all the provisions of this Agreement shall be deemed null and void, except that the statute of limitations for any prosecution relating to the conduct described in the Statement of Facts shall be tolled from the date on which this Agreement is signed until the date the Court refuses to grant the exclusion of time plus six months, and except for the provisions contained within Paragraph 2 of this Agreement.

# **Relevant Considerations**

- 4. The Government enters into this Agreement based on the individual facts and circumstances presented by this case and the Company, including:
  - a. the nature of the conduct described in the attached Statement of Facts, which involved the sale of misbranded food in violation of the Food, Drug, and Cosmetic

Act ("FDCA"), and several offenses under Title 18 of the United States Code;

- b. the Company did not receive voluntary disclosure credit because it did not timely and voluntarily disclose to the Government the conduct described in the Statement of Facts;
- c. the Company was sold in an arms-length transaction to an independent third party subsequent to the conduct described in the Statement of Facts, and new ownership was unaware of the Company's violative conduct at the time of the sale despite having performed reasonable due diligence. Furthermore, the government was unaware of the sale until after key stages of the investigation had already transpired, including the execution of a premises search warrant that uncovered evidence of the Company's violative conduct prior to the just-completed sale;
- d. the Company, beginning in 2016, under the direction of new ownership, provided to the Government all relevant facts known to it, including information about the individuals involved in the conduct described in the attached Statement of Facts and conduct disclosed prior to the Agreement;
  - e. the Company engaged in remedial measures, including:
  - i. overhauling the Company's management structure and vendor relationships to emphasize compliance and stricter management controls;
  - ii. engaging in a comprehensive labeling and ingredient review in consultation with a recognized third-party compliance consultant with FDA experience;
  - iii. imposing stricter manufacturing controls over all contract manufacturers designed to ensure that products are manufactured according to

specifications; and

- iv. creating and implementing a comprehensive regulatory review and compliance plan;
- f. the Company enhanced and has committed to continuing to enhance its compliance program and internal controls, including ensuring that its compliance program satisfies the minimum elements set forth in Attachment C to this Agreement (Corporate Compliance Program);
- g. the Company has agreed to continue to cooperate with the Government as described in Paragraph 5, below;
  - h. the Company has no prior criminal history;
- i. accordingly, after considering (a) through (h) above, the Government believes that the appropriate resolution in this case is a Deferred Prosecution Agreement with the Company; and a criminal monetary penalty in the amount of \$50,000, which reflects a fine at the high end of the otherwise applicable Sentencing Guidelines fine range and consideration of the Company's ability to pay.

### **Future Cooperation and Disclosure Requirements**

5. The Company and its subsidiaries and affiliates shall cooperate fully with the Government in any and all matters relating to the conduct described in this Agreement and the attached Statement of Facts and to other conduct in violation of the FDCA, Title 21, United States Code, Section 301 *et seq.*, until the later of the date upon which all investigations and potential prosecutions arising out of such conduct are concluded or the end of the Term. At the request of the Government, the Company and its subsidiaries and affiliates shall also cooperate fully with other domestic or foreign law enforcement and regulatory authorities and agencies in any

investigation of the Company, its parent company or its affiliates, or any of its present or former officers, directors, employees, agents, and consultants, or any other party, in any matters relating to the conduct described in this Agreement, the attached Statement of Facts, and other conduct under investigation by the Government. The Company's cooperation pursuant to this paragraph is subject to applicable law and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine; however, the Company must provide to the Government a log of any information or cooperation that is not provided based on an assertion of law, regulation, or privilege, and the Company bears the burden of establishing the validity of any such assertion. The Company agrees that its cooperation pursuant to this paragraph shall include, but not be limited to, the following:

- a. Upon request of the Government, the Company and its subsidiaries and affiliates shall truthfully disclose all factual information with respect to their activities and those of their present and former directors, officers, employees, agents, and consultants, including any evidence or allegations and internal or external investigations, about which the Company and its subsidiaries and affiliates have any knowledge or about which the Government may inquire. This obligation of truthful disclosure includes, but is not limited to, the obligation of the Company and its subsidiaries and affiliates to provide to the Government, upon request, any document, record or other tangible evidence about which the Government may inquire of the Company and its subsidiaries and affiliates;
- b. Upon request of the Government, the Company and its subsidiaries and affiliates shall designate knowledgeable employees, agents or attorneys to provide to the Government the information and materials described in Paragraph 5(a) above on behalf of the Company and its subsidiaries and affiliates. It is further understood that the Company

and its subsidiaries and affiliates must at all times provide complete, truthful, and accurate information.

- c. The Company and its subsidiaries and affiliates shall use their best efforts to make available for interviews or testimony, as requested by the Government, former, present and future officers, directors, employees, agents and consultants of the Company and its subsidiaries and affiliates. This obligation includes, but is not limited to, sworn testimony before a federal grand jury or in federal trials, as well as interviews with law enforcement and regulatory authorities. Cooperation under this paragraph shall include identification of witnesses who, to the knowledge of the Company and its subsidiaries and affiliates, may have material information sought by the Government;
- d. With respect to any information, testimony, documents, records or other tangible evidence provided to the Government pursuant to this Agreement, the Company and its subsidiaries and affiliates consent to any and all disclosures to other governmental authorities, including United States authorities and those of a foreign government of such materials as the Government, in its sole discretion, shall deem appropriate;
- 6. In addition to the obligations in Paragraph 5, during the Term, should the Company learn of any evidence or allegation of a violation of the FDCA committed by the Company's employees or agents which is within the jurisdiction of any domestic government agency (including the United States Food and Drug Administration), the Company shall promptly report such evidence or allegation to the Government.

#### **Total Criminal Monetary Amount**

7. The Company and the Government agree that the Total Criminal Monetary Amount to be paid by the Company pursuant to this Agreement is \$50,000. This amount reflects the

Government's consideration of the Company's ability to pay a monetary amount.

8. The Company acknowledges that no tax deduction may be sought in connection with the payment of the Criminal Monetary Penalty. The Company shall not seek or accept directly or indirectly reimbursement or indemnification from any source with regard to the Criminal Monetary Penalty or any other agreement entered into with any other enforcement authority or a regulator concerning the facts set forth in the Statement of Facts.

## **Payment of Criminal Monetary Penalty**

- 9. The Company agrees to pay the Criminal Monetary Penalty in the amount of \$50,000 to the United States Treasury no later than thirty (30) days after the signing of this agreement pursuant to payment instructions provided by the Government in its sole discretion. The Company and the Government agree that the Criminal Monetary Penalty is appropriate given the facts and circumstances of this case, including the Relevant Considerations described in Paragraph 4 of this Agreement.
- 10. The Criminal Monetary Penalty is final and shall not be refunded. Furthermore, nothing in this Agreement shall be deemed an agreement by the Government that \$50,000 is the maximum fine that may be imposed in any future prosecution, and the Government is not precluded from arguing in any future prosecution that the Court should impose a higher fine, although the Government agrees that under those circumstances, it will recommend to the Court that any amount paid as part of the Criminal Monetary Penalty should be offset against any fine the Court imposes as part of a future judgment.

#### **Conditional Release from Liability**

11. Subject to Paragraphs 18-19 below, the Government agrees, except as provided in this Agreement, that it will not bring any criminal case against the Company relating to any of the

conduct described in the attached Statement of Facts described in Attachment A. The Government, however, may use any information related to the conduct described in the attached Statement of Facts against the Company: (a) in a prosecution for perjury or obstruction of justice; (b) in a prosecution for making a false statement; (c) in a prosecution or other proceeding relating to any crime of violence; or (d) in a prosecution or other proceeding relating to a violation of any provision of Title 26 of the United States Code.

- 12. This Agreement does not provide any protection against prosecution for any future conduct by the Company.
- 13. In addition, this Agreement does not provide any protection against prosecution of any individuals, regardless of their affiliation with the Company.

# **Corporate Compliance Program**

- 14. The Company represents that it has implemented and will continue to implement a compliance program designed to detect and prevent the introduction into interstate commerce of misbranded or adulterated supplements in violation of the FDCA, throughout its operations, including those of its affiliates, agents, and joint ventures, and those of its contractors and subcontractors, including, but not limited to, the elements set forth in Attachment C of this Agreement.
- 15. In order to address any deficiencies in its internal controls, policies, and procedures, the Company represents that it has undertaken, and will continue to undertake in the future, in a manner consistent with all of its obligations under this Agreement, a review of its existing controls, policies, and procedures regarding compliance with the FDCA. Where necessary and appropriate, the Company agrees to adopt a new compliance program, or to modify its existing one, including internal controls, compliance policies, and procedures to ensure that it maintains an effective

compliance program, including a system of internal controls designed to effectively detect and deter violations of the FDCA. The compliance program, including the internal controls system, will include, but not be limited to, the elements set forth in Attachment C of this Agreement.

# **Corporate Compliance Reporting**

- 16. The Company represents that it has implemented and will continue to implement a compliance program designed to prevent and detect violations of the FDCA throughout its operations, including those of its affiliates, agents, and joint ventures (to the extent the company manages or controls such joint ventures), including, but not limited to, the minimum elements set forth in Attachment C.
- 17. In order to address any deficiencies in its internal controls, policies, and procedures, the Company represents that it has undertaken, and will continue to undertake in the future, in a manner consistent with all of its obligations under this Agreement, a review of its existing controls, policies, and procedures regarding compliance with the FDCA. Where necessary and appropriate, the Company agrees to adopt a new compliance program, or to modify its existing one, including internal controls, compliance policies, and procedures designed to ensure that it maintains an effective compliance program, including a system of internal controls, designed to effectively detect and deter violations of the FDCA. The compliance program, including the internal controls system, will include, but not be limited to, the minimum elements set forth in Attachment C.

#### **Deferred Prosecution**

18. In consideration of the undertakings agreed to by the Company herein, the Government agrees that any prosecution of the Company for the conduct set forth in the attached Statement of Facts or Information will be and hereby is deferred for the Term. To the extent there

is conduct disclosed by the Company that is not set forth in the attached Statement of Facts or Information, such conduct will not be exempt from further prosecution and is not within the scope of or relevant to this Agreement.

19. The Government further agrees that if the Company fully complies with all of its obligations under this Agreement, the Government will not continue the criminal prosecution against the Company described in Paragraph 1 and, at the conclusion of the Term, this Agreement shall expire. Six months after the Agreement's expiration, the Government shall seek dismissal with prejudice of the Information filed against the Company described in Paragraph 1, and agree not to file charges in the future against the Company based on the conduct described in this Agreement, the attached Statement of Facts, or the Information. If, however, the Government determines during this six-month period that the Company breached the Agreement during the Term, as described in Paragraph 20, the Government's ability to extend the Term, as described in Paragraphs 20-22, remains in full effect.

# **Breach of the Agreement**

20. If, during the Term, (a) the Company commits any felony under U.S. federal law; (b) the Company provides in connection with this Agreement deliberately false, incomplete, or misleading information, including in connection with its disclosure of information about individual culpability; (c) the Company or its subsidiaries and affiliates fail to cooperate as set forth in Paragraphs 5 and 6 of this Agreement; (d) the Company fails to implement a compliance program as set forth in Paragraphs 14-15 of this Agreement and Attachment C; or (e) the Company and its subsidiaries and affiliates otherwise fail to completely perform or fulfill each of their obligations under the Agreement, regardless of whether the Government becomes aware of such a breach after

the Term is complete, the Company and its subsidiaries and affiliates shall thereafter be subject to prosecution for any federal criminal violation of which the Government has knowledge, including, but not limited to, the charges in the Information described in Paragraph 1, which may be pursued by the Government in the United States District Court for the Northern District of Texas or any other appropriate venue. Determination of whether the Company has breached the Agreement and whether to pursue prosecution of the Company and its subsidiaries and affiliates shall be in the Government's sole discretion. Any such prosecution may be premised on information provided by the Company, its subsidiaries and affiliates, or their personnel. Any such prosecution relating to the conduct described in the attached Statement of Facts or relating to conduct known to the Government prior to the date on which this Agreement was signed that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced against the Company, or its subsidiaries and affiliates, notwithstanding the expiration of the statute of limitations, between the signing of this Agreement and the expiration of the Term plus one year. Thus, by signing this Agreement, the Company agrees that the statute of limitations with respect to any such prosecution that is not time-barred on the date of the signing of this Agreement shall be tolled for the Term plus one year. In addition, the Company agrees that the statute of limitations as to any violation of U.S. federal law that occurs during the Term will be tolled from the date upon which the violation occurs until the earlier of the date upon which the Government is made aware of the violation or the duration of the Term plus five years, and that this period shall be excluded from any calculation of time for purposes of the application of the statute of limitations.

21. In the event the Government determines that the Company has breached this Agreement, the Government agrees to provide the Company with written notice of such breach prior to instituting any prosecution resulting from such breach. Within thirty days of receipt of

such notice, the Company shall have the opportunity to respond to the Government in writing to explain the nature and circumstances of such breach, as well as the actions the Company has taken to address and remediate the situation, which explanation the Government shall consider in determining whether to pursue prosecution of the Company.

- 22. In the event that the Government determines that the Company has breached this Agreement: (a) all statements made by or on behalf of the Company or its subsidiaries and affiliates to the Government or to the Court, including the attached Statement of Facts, and any testimony given by the Company or its subsidiaries and affiliates before a grand jury, a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings brought by the Government against the Company or its subsidiaries and affiliates; and (b) the Company or its subsidiaries and affiliates shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, Section 1B1.1(a) of the USSG, or any other federal rule that any such statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible. The decision whether conduct or statements of any current director, officer, or employee, or any person acting on behalf of, or at the direction of, the Company or its subsidiaries and affiliates will be imputed to the Company for the purpose of determining whether the Company has violated any provision of this Agreement shall be in the sole discretion of the Government.
- 23. The Company acknowledges that the Government has made no representations, assurances, or promises concerning what sentence may be imposed by the Court if the Company breaches this Agreement and this matter proceeds to judgment. The Company further

acknowledges that any such sentence is solely within the discretion of the Court and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion.

24. On the date that the period of deferred prosecution specified in this Agreement expires, the Company, by the Chief Executive Officer of the Company, will submit the certification set forth in Attachment D and certify to the Government that the Company has met its disclosure obligations pursuant to Paragraph 6 of this Agreement. The certification will be deemed a material statement and representation by the Company to the executive branch of the United States for purposes of Title 18, United States Code, Sections 1001 and 1519, and it will be deemed to have been made in the judicial district in which this Agreement is filed.

# Sale, Merger, or Other Change in Corporate Form of the Company

transaction, the Company agrees that in the event that, during the Term, it undertakes any change in corporate form, including if it sells, merges, or transfers business operations that are material to the Company's consolidated operations, or to the operations of any subsidiaries or affiliates involved in the conduct described in the Statement of Facts, as they exist as of the date of this Agreement, whether such sale is structured as a sale, asset sale, merger, transfer, or other change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. The purchaser or successor in interest must also agree in writing that the Government's ability to declare breach under this Agreement is applicable in full force to the purchaser or successor in interest. The Company agrees that the failure to include these provisions in the transaction will make any such transaction null and void. The Company shall provide notice to the Government at least thirty days prior to undertaking any such sale, merger,

transfer, or other change in corporate form. The Government shall notify the Company prior to such transaction (or series of transactions) if it determines that the transaction(s) will have the effect of circumventing or frustrating the enforcement purposes of this Agreement. If, at any time during the Term, the Company engages in a transaction that has the effect of circumventing or frustrating the enforcement purposes of this Agreement, the Government may deem it a breach of this Agreement pursuant to Paragraphs 20-22 of this Agreement. Nothing in this Agreement shall restrict the Company from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined by the Government.

## **Public Statements by the Company**

26. The Company expressly agrees that it shall not, through present or future attorneys, officers, directors, agents, management level employees or any other person authorized to speak for the Company, make any public statement, in litigation or otherwise, contradicting in whole or in part the acceptance of responsibility by the Company set forth above or the facts described in the attached Statement of Facts. Any such contradictory statement shall, subject to cure rights of the Company described in this paragraph below, constitute a material breach of this Agreement, and the Company thereafter shall be subject to prosecution as set forth in this Agreement. The decision whether any public statement by any such person contradicting a fact contained in the Statement of Facts will be imputed to the Company for the purpose of determining whether it has breached this Agreement shall be at the sole discretion of the Government. If the Government determines that a public statement by any such person contradicts in whole or in part a statement

contained in the Statement of Facts, the Government shall so notify the Company, and the Company may avoid a breach of this Agreement by publicly repudiating such statement(s) within five business days after notification. The Company shall be permitted to raise defenses and to assert affirmative claims in other proceedings relating to the matters set forth in the Statement of Facts provided that such defenses and claims do not contradict, in whole or in part, a statement contained in the Statement of Facts. This Paragraph does not apply to any statement made by any present or former officer, director, employee, or agent of the Company in the course of any criminal, regulatory, or civil case initiated against such individual, unless such individual is speaking on behalf of the Company.

- 27. The Company agrees that if it or any of its direct or indirect subsidiaries or affiliates issues a press release or holds any press conference in connection with this Agreement, the Company shall first consult with the Government to determine: (a) whether the text of the release or proposed statements at the press conference are true and accurate with respect to matters between the Government and the Company; and (b) whether the Government has any objection to the release.
- 28. The Government agrees, if requested to do so, to bring to the attention of law enforcement and regulatory authorities the facts and circumstances relating to the nature of the conduct underlying this Agreement, including the nature and quality of the Company's cooperation and remediation. By agreeing to provide this information to such authorities, the Government is not agreeing to advocate on behalf of the Company, but rather is agreeing to provide facts to be evaluated independently by such authorities.

#### **Limitations on Binding Effect of Agreement**

29. This Agreement is binding on the Company, the United States Attorney's Office

for the Northern District of Texas, and the Consumer Protection Branch, but specifically does not bind any other component of the Department of Justice, other federal agencies, or any state, local or foreign law enforcement or regulatory agencies, or any other authorities, although the Government will bring the cooperation of the Company and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company.

### **Notice**

30. Any notice to the Government under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to:

Chief, Criminal Division U.S. Attorney's Office Northern District of Texas 1100 Commerce St., Third Floor Dallas, TX 75242

Director, Consumer Protection Branch Civil Division U.S. Department of Justice 450 5th Street NW, Room 6400 South Washington, DC 20001

31. Any notice to the Company under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to:

ProSupps USA LLC 5757 Main Street, Suite 205 Frisco, TX 75034

32. Notice shall be effective upon actual receipt by the Government or the Company.

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# **Complete Agreement**

33. This Agreement, including its attachments, sets forth all the terms of the agreement between the Company and the Government. No amendments, modifications or additions to this Agreement shall be valid unless they are in writing and signed by the Government, the attorneys for the Company and a duly authorized representative of the Company.

AGREED:	
FOR PROSUPPS USA INC.:	
Date: 8-20-21	By:  Robert Reynolds  Executive Chairman/Chief Executive Officer ProSupps USA LLC.
Date:	By:  Joseph F. Savage, Jr.  Goodwin Procter LLP  Counsel for ProSupps USA LLC.

# **Complete Agreement**

33. This Agreement, including its attachments, sets forth all the terms of the agreement between the Company and the Government. No amendments, modifications or additions to this Agreement shall be valid unless they are in writing and signed by the Government, the attorneys for the Company and a duly authorized representative of the Company.

AGREED:	
FOR PROSUPPS USA INC.:	
Date:	By:Robert Reynolds Executive Chairman/Chief Executive Officer ProSupps USA LLC.
Date: 8/20/21	By:  Joseph F. Savage, Jr.  Goodwin Procter LLP  Counsel for ProSupps USA LLC.

FOR THE U.S. DEPARTMENT OF JUSTICE, CONSUMER PROTECTION BRANCH:

Date: August 24, 2021

Gustav W. Eyler

Director

Alan D. Phelps *Deputy Director* 

David Sullivan Patrick R. Runkle *Trial Attorneys* 

FOR THE U.S. ATTORNEY'S OFFICE, NORTHERN DISTRICT OF TEXAS:

Date: 08/25/2021

Prerak Shall

Acting United States Attorney

Douglas Brasher Assistant U.S. Attorney

COMPANY OFFICER'S CERTIFICATE

I have read this A greement and carefully reviewed every part of it with outside counsel

for ProSupps USA LLC (the "Company"). I understand the terms of this Agreement and

y oluntarily agree, on behalf of the Company, to each of its terms. Before signing this A greement.

I consulted outside counsel for the Company. Counsel fully advised me of the rights of the

Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the

consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Managers of the

Company. I have caused outside counsel for the Company to advise the Managers fully of the

rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of

the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in this

Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person

authorizing this Agreement on behalf of the Company, in any way to enter into this Agreement.

I am also satisfied with outside counsel's representation in this matter. I certify that I am the

Executive Chairman/Chief Executive Officer of the Company and that I have been duly

authorized by the Company to execute this Agreement on behalf of the Company.

Date: &- 26 2

11/1/11/

Robert Reynold

Executive Chairman/Chief Executive Officer

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**CERTIFICATE OF COUNSEL** 

I am counsel for ProSupps USA LLC (the "Company") in the matter covered by this Agreement. In connection with such representation, I have examined relevant Company documents and have discussed the terms of this Agreement with the Company's Managers. Based on our review of the foregoing materials and discussions, I am of the opinion that the representative of the Company has been duly authorized to enter into this Agreement on behalf of the Company and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of the Company and is a valid and binding obligation of the Company. Further, I have carefully reviewed the terms of this Agreement with the Managers of the Company. I have fully advised them of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions and of the consequences of entering into this Agreement. To my knowledge, the decision of the

Company to enter into this Agreement, based on the authorization of the Managers, is

Date:	8/20/21	

an informed and voluntary one.

By:

Joseph F. Savage, Jr. Goodwin Procter LLP

#### **ATTACHMENT A**

## **STATEMENT OF FACTS**

The investigation conducted by the Government to date has determined the facts set forth below. ProSupps accepts that it is responsible for its acts as described herein.

- At all times relevant to the investigation, ProSupps was in the business of creating and selling products marketed as dietary supplements in, among other things, the "preworkout" sector of the supplement industry.
- In November 2015, FDA warned several companies in the supplement industry that the ingredient picamilon appeared not to be a legal dietary ingredient under the Food, Drug, and Cosmetic Act.
- 3. Prior to April 2016, many versions of the ProSupps products Mr. Hyde, Dr. Jekyll, and Vanish contained picamilon as an ingredient.
- 4. In or around late 2015 and early 2016, ProSupps introduced into interstate commerce shipments containing approximately 240,000 units of Mr. Hyde, Dr. Jekyll, and Vanish. Through a series of actions and omissions indicating, at the very least, that ProSupps lacked control over its own inventory processes, these units of picamilon-containing product had been returned from a vendor and were incorrectly relabeled as not containing picamilon when they, in fact, did contain picamilon.
- 5. In April 2016, ProSupps initiated a consumer recall of its picamilon-containing products.
- In or around August 2016, ProSupps introduced additional shipments of picamiloncontaining Mr. Hyde into interstate commerce containing approximately 7,200 units of product.

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7. The shipments described in paragraphs 4 and 6 were misbranded because the products contained the ingredient picamilon, which was not declared on the product labeling.

#### ATTACHMENT B

# <u>CERTIFICATE OF CORPORATE RESOLUTIONS – PROSUPPS USA LLC.</u>

WHEREAS, ProSupps USA LLC (the "Company") has been engaged in discussions with the United States Department of Justice, Civil Division, Consumer Protection Branch and the United States Attorney's Office for the Northern District of Texas (collectively, the "Government") regarding issues arising in relation to the sale of products marketed as dietary supplements; and

WHEREAS, in order to resolve such discussions, it is proposed that the Company enter into a certain agreement with the Government (the "Agreement");

WHEREAS, outside counsel for the Company has advised the Managers of the Company (the "Managers") of the Company's rights, possible defenses, the provisions of the U.S. Sentencing Guidelines, and the consequences of entering into such agreement with the Government;

Therefore, the Managers have RESOLVED that:

- 1. The Company (a) acknowledges the filing of the Information charging the Company with one count of introduction of a misbranded food into interstate commerce in violation of Title 21, United States Code, Section 331(a); (b) waives indictment on such charges and enters into a deferred prosecution agreement with the Government; and (c) agrees to pay \$50,000.
- 2. The Company accepts the terms and conditions of this Agreement, including, but not limited to: (a) a knowing waiver of its rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); and (b) a knowing waiver for purposes of this

Agreement and any charges by the United States arising out of the conduct described in the Statement of Facts of any objection with respect to venue and consents to the filing of the Information, as provided under the terms of this Agreement, in the United States District Court for the Northern District of Texas; and, (c) a knowing waiver of any defenses based on the statute of limitations for any prosecution relating to the conduct described in the Statement of Facts or relating to conduct known to the Government prior to the date on which this Agreement was signed that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement;

- 3. The Company's Executive Chairman/Chief Executive Officer, Robert Reynolds, is hereby authorized, empowered and directed, on behalf of the Company, to execute the Agreement substantially in such form as reviewed by the Managers with such changes as Mr. Reynolds, may approve;
- 4. Mr. Reynolds, and any other officer of ProSupps designated by Mr. Reynolds in writing and with notice to the Government, is hereby authorized, empowered and directed to take any and all actions as may be necessary or appropriate and to approve the forms, terms or provisions of any agreement or other documents as may be necessary or appropriate, to carry out and effectuate the purpose and intent of the foregoing resolutions; and
- 5. All of the actions of Mr. Reynolds, which actions would have been authorized by the foregoing resolutions except that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved, and adopted as actions on behalf of the Company.

Date: August 20, 2021

Alison Minter ProSupps USA LLC

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Bv:

#### ATTACHMENT C

#### **CORPORATE COMPLIANCE PROGRAM**

In order to address any deficiencies in its internal controls, compliance policies and procedures regarding violations of the Federal Food, Drug, and Cosmetic Act, Title 21, United States Code, Section 301 *et seq.* (the "FDCA"), ProSupps USA LLC (the "Company") agrees to continue to conduct, in a manner consistent with all of its obligations under this Agreement, appropriate reviews of its existing internal controls, policies, and procedures.

Where necessary and appropriate, the Company agrees to adopt a new or to modify its existing compliance program, including internal controls, compliance policies, and procedures designed to maintain an effective compliance program that is designed, implemented, and enforced to effectively deter and detect violations of the FDCA. At a minimum, this should include, but not be limited to, the following elements to the extent they are not already part of the Company's existing internal controls, compliance program, policies, and procedures:

## Commitment to Compliance

1. The Company will ensure that its directors and senior management provide strong, explicit, and visible support and commitment to its corporate policy against violations of the FDCA or the Company's compliance policy, and demonstrate rigorous adherence by example. The Company will also implement policies and procedures designed to ensure that middle management, in turn, reinforces those standards and encourages employees to abide by them. The Company will create and foster a culture of ethics and compliance with the law in its day-to-day operations.

#### Policies and Procedures

- 2. The Company will develop and promulgate clearly articulated and visible corporate policies against violations of the FDCA, which policies shall be memorialized in writing. Among other things, these policies will include a prohibition on using ingredients that FDA has declared unlawful for use in dietary supplements as well as ingredients that are the subject of public FDA warning letters or import alerts related to dietary supplements.
- 3. The Company will develop and promulgate compliance policies and procedures designed to reduce the prospect of violations of the FDCA and the Company's compliance policies and procedures, and the Company will take appropriate measures to encourage and support the observance of ethics and compliance policies and procedures against violation of the FDCA by personnel at all levels of the Company. These policies and procedures shall apply to all directors, officers, and employees and, where necessary and appropriate, outside parties acting on behalf of the Company, including, but not limited to, agents, consultants, and joint venture partners (collectively, "agents and business partners"). The Company shall notify all employees that compliance with the policies and procedures is the duty of individuals at all levels of the Company.

#### Periodic Risk-Based Review

- 4. The Company will develop these compliance policies and procedures on the basis of a periodic risk assessment addressing the individual circumstances of the Company.
- 5. The Company shall review its compliance policies and procedures regarding the FDCA no less than annually and update them as appropriate to ensure its continued effectiveness, taking into account relevant developments in the field and evolving industry standards.

#### Proper Oversight and Independence

6. The Company will assign responsibility to one or more senior corporate executives of the Company for the implementation and oversight of the Company's compliance policies and procedures regarding the FDCA. Such corporate official(s) shall have the authority to report directly to independent monitoring bodies, including internal audit, the Company's Board of Directors, or any appropriate committee of the Board of Directors, and shall have an adequate level of stature and autonomy from management as well as sufficient resources and authority to maintain such autonomy.

### Training and Guidance

- 7. The Company will implement mechanisms designed to ensure that its compliance policies and procedures regarding the FDCA are effectively communicated to all directors, officers, employees, and, where necessary and appropriate, agents and business partners. These mechanisms shall include: (a) periodic training for all directors and officers, all employees in positions of leadership or trust, any positions that require such training (*e.g.*, internal audit, sales, legal, compliance, finance), and, where necessary and appropriate, agents and business partners; and (b) corresponding documentation by all such directors, officers, employees, agents and business partners, attesting to compliance with the training requirements. The Company will conduct training in a manner tailored to the audience's size, sophistication, and subject-matter expertise and, where appropriate, will discuss prior compliance incidents.
- 8. The Company will maintain, or where necessary establish, an effective system for providing guidance and advice to directors, officers, employees, and, where necessary and appropriate, agents and business partners, on complying with the Company's compliance

policies and procedures regarding the FDCA, including when they need advice on an urgent basis.

#### *Internal Reporting and Investigation*

- 9. The Company will maintain, or where necessary establish, an effective system for internal and, where possible, confidential reporting by, and protection of, directors, officers, employees, and, where appropriate, agents and business partners concerning violations of the FDCA or the Company's compliance policies and procedures regarding the FDCA.
- 10. The Company will maintain, or where necessary establish, an effective and reliable process with sufficient resources for responding to, investigating, and documenting allegations of violations of the FDCA or the Company's compliance policies and procedures regarding the FDCA. The Company will handle the investigations of such complaints in an effective manner, including routing the complaints to proper personnel, conducting timely and thorough investigations, and following up with appropriate discipline where necessary.

#### Enforcement and Discipline

- 11. The Company will implement mechanisms designed to effectively enforce its compliance policies and procedures, including appropriately incentivizing compliance and disciplining violations.
- 12. The Company will institute appropriate disciplinary procedures to address, among other things, violations of the FDCA and the Company's compliance policies and procedures regarding the FDCA by the Company's directors, officers, and employees. Such procedures should be applied consistently and fairly, and in a manner consistent with the violation, regardless of the position held by, or perceived importance of, the director, officer, or employee. The Company shall implement procedures designed to ensure that where violative conduct is

discovered, reasonable steps are taken to remedy the harm resulting from such violative conduct, and that appropriate steps are taken to prevent further similar violative conduct, including assessing the internal controls, compliance policies and procedures and making modifications necessary to ensure the Company's overall compliance program regarding the FDCA is effective.

#### Mergers and Acquisitions

- 13. The Company will develop and implement policies and procedures for mergers and acquisitions requiring that the Company conduct appropriate risk-based due diligence on potential new business entities, including appropriate due diligence regarding the FDCA by legal, accounting, and compliance personnel.
- 14. The Company will apply its compliance policies and procedures regarding the FDCA as quickly as is practicable to newly-acquired businesses or entities merged with the Company, and will promptly (a) train the directors, officers, employees, agents, and business partners consistent with Paragraphs 7-8; and (b) where warranted, conduct an audit of all newly acquired or merged businesses as quickly as is practicable concerning compliance with the FDCA.

## Monitoring, Testing, and Remediation

15. In order to ensure that its compliance program does not become stale, the Company will conduct at least annual reviews and testing of its compliance policies and procedures regarding the FDCA designed to evaluate and improve its effectiveness in preventing and detecting violations of the FDCA and the Company's policies and procedures regarding the FDCA, taking into account relevant developments in the field and evolving industry standards. The Company will ensure that compliance and control personnel have sufficient direct and

indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing. Based on such review and testing and its analysis of any prior violative conduct, the Company will conduct a reasonable root-cause analysis and timely and appropriately remediate any detected root causes of violative conduct.

#### ATTACHMENT D

## <u>CERTIFICATION – PROSUPPS USA LLC</u>

To: Chief, Criminal Division	Director	
U.S. Attorney's Office	Consumer Protection Branch, Civil Division	
Northern District of Texas	United States Department of Justice	
	-	

Re: Deferred Prosecution Agreement Disclosure Certification

The undersigned certifies, pursuant to Paragraph 6 of the Deferred Prosecution Agreement (the "Agreement") filed in August 2021 in the United States District Court for the Northern District of Texas, by and between the United States of America and ProSupps USA LLC (the "Company"), that undersigned is aware of the Company's disclosure obligations under Paragraph 6 of the Agreement, and that the Company has disclosed to the United States Attorney's Office for the Northern District of Texas and the United States Department of Justice, Civil Division, Consumer Protection Branch (collectively the "Government") any and all evidence or allegations of conduct required pursuant to Paragraph 6 of the DPA, which includes evidence or allegations that may constitute a violation of U.S. laws regarding the marketing, sale, importation, or distribution of purported dietary supplements and dietary supplement ingredients ("Disclosable Information"). This obligation to disclose information extends to any and all Disclosable Information that has been identified through the Company's compliance and controls program, whistleblower channel, internal audit reports, due diligence procedures, investigation process, or other processes. The undersigned further acknowledges and agrees that the reporting requirements contained in Paragraph 6 and the representations contained in this certification

constitute a significant and important component of the Agreement and of the Government's determination whether the Company has satisfied its obligations under the Agreement.

The undersigned hereby certifies that he is the Chief Executive Officer, and that he has been duly authorized by the Company to sign this Certification on behalf of the Company.

This Certification shall constitute a material statement and representation by the undersigned and by, on behalf of, and for the benefit of, the Company to the executive branch of the United States for purposes of 18 U.S.C. § 1001, and such material statement and representation shall be deemed to have been made in the Northern District of Texas. This Certification shall also constitute a record, document, or tangible object in connection with a matter within the jurisdiction of a department and agency of the United States for purposes of 18 U.S.C. § 1519, and such record, document, or tangible object shall be deemed to have been made in the Northern District of Texas.

Dated: 8-20-21

By:

Robert Reynolds

Executive Chairman/Chief Executive Officer

ProSupps USA LLC